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10/081,955	02/20/2002	George Seidel	XY-Super-Cont2	2282
33549	7590	02/27/2009	EXAMINER	
SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	
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			02/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/081,955	SEIDEL ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124,133,136 and 139-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124,133,136 and 139-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2008 has been entered.

2. This action is in response to the amendment filed November 24, 2008. Applicant's arguments have been fully considered but are not persuasive to place all claims in condition for allowance.

All rejections not reiterated herein are hereby withdrawn. In particular, the objection to the amendment filed February 13, 2008 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure has been obviated by the amendment to delete this subject matter from the specification. Further, the previous rejections under 35 USC 112 first paragraph (new matter and enablement) have been obviated by the amendments to the claims.

This action contains new grounds of rejection necessitated by Applicant's amendments to the claims and is made non-final.

3. Claims 124, 133, 136 and 139-141 are pending and have been examined herein.

Information Disclosure Statement

4. The information disclosure statement filed November 24, 2008 fails to comply with 37 CFR 1.98(a)(3) because each of the references that have been lined through do not include a date of publication. That is, the date of publication has not been listed in the IDS and the date of publication is not provided on the cited references. Several of the references also do not list a place of publication. It has been placed in the application file, but the information referred to therein has not been considered.

Note that 37 CFR 1.98(b)(5) requires that "(e)ach publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication." MPEP 609.04(a) further states that "(t)he date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published." Without information regarding the date of publication, the relevance of the cited reference to the claimed invention cannot be determined.

Claim Objections

5. Claim 124 is objected to because of the following informalities:

In claim 124, an "and" should be inserted following "h.mammals;" and prior to "i. producing..".

Appropriate correction is required.

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification does not provide proper antecedent basis for the claimed subject matter of an insemination sample having 618,240 sperm (claim 124, step f)). The specification (page 23) teaches an insemination sample consisting of 184ul of sorted sperm at a concentration 3.36×10^6 sperm/ml, but this teaching does not provide clear antecedent basis for the recitation of an insemination sample having 618,240 sperm. Further, the specification does not provide clear antecedent basis for fertilizing eggs in 75% of multiple bovine mammals (claim 124, step h)). The specification (page 23) teaches recovering embryos in 9 out of 12 bovine. However, this disclosure does not provide clear antecedent basis for the claimed subject matter of fertilizing eggs in 75% of bovine mammals.

As stated in 608.01(O), "While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, Ex parte Kotler, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01."

Claim Rejections - 35 USC § 112 – New Matter

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124, 133, 136 and 139-141 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not appear to provide support for the claimed methods of producing multiple embryos from multiple female bovine wherein the methods comprise:

- a) sorting sperm cells at a rate "of about 800 live sperm of each sex per second"
- b) concentrating sperm cells to a concentration of "about 3.36×10^6 sperm/ml"
- c) establishing an insemination sample having a volume of "about 184 microliters" each sample having "about 618,240 of said sperm cells" and
- d) fertilizing a plurality of said eggs "in each of up to 75% of said multiple female bovine mammals."

In the reply of November 24, 2008, Applicants state that support for the amendments to the claims is found at pages 22-23 of the specification. However, the

example at pages 22-23 of the specification does not provide support for each of the limitations recited above.

In particular, regarding the recitation "of about 800 live sperm of each sex per second," the specification (page 23) provides support only for the concept of sorting to yield "700-800 live sperm of each sex/sec." The term "about" is not defined in the specification and there is no indication that "about 800" is intended to be limited to only 700-800, as opposed to 695 or 805 or 820 live sperm/sec. Accordingly, the disclosure of the particular concept of "700-800 live sperm of each sex/sec" does not provide support for the broader concept of "about 800 live sperm per second."

Regarding the recitation of concentrating sperm cells to a concentration of "about 3.36×10^6 sperm/ml," the specification (page 23) provides support only for the concept of concentrating the sperm cells to a concentration of 3.36×10^6 sperm/ml. The specification does not provide any teachings which indicate that "about" is intended to mean "exactly" such that "about 3.36×10^6 sperm/ml" would mean only " 3.36×10^6 sperm/ml." Further, the specification does not appear to teach that other concentrations of "about 3.36×10^6 sperm/ml" are to be used in the specific method recited in the claims.

Regarding the recitation of establishing an insemination sample having a volume of "about 184 microliters" each sample having "about 618,240 of said sperm cells," the specification (page 23) teaches insemination sample volumes of 184 microliters. However, this disclosure of a single species does not provide basis for the broader concept of a volume of "about 184 microliters" (i.e., 180, 181, 185, 186 etc microliters).

The specification also teaches that an insemination sample of 184 microliters of sorted sperm at a concentration 3.36×10^6 sperm/ml is used to inseminate 12 superovulated angus heifers. Thereby, the specification provides support for the concept of an insemination sample in which there is 618,240 sorted sperm. This disclosure does not provide basis for the broader concept claimed of "about 618,240 of said sperm cells of a desired sex." Again, the specification does not provide any teachings which indicate that "about 618,240" sorted sperm is intended to be limited to exactly 618,240 sorted sperm. Further, there are no apparent teaches in the specification which indicate that quantities of sperm encompassed by "about 618,240" sorted sperm are to be used in the specific method recited in the claims.

Regarding the recitation of fertilizing a plurality of said eggs "in each of up to 75% of said multiple female bovine mammals," the specification (page 23) teaches that, in the exemplified method, embryos were recovered from 9 out of 12 inseminated heifers. Thereby, the specification provides support for the concept of fertilizing eggs in 9 of 12 female bovine mammals. However, this disclosure does not provide support for the broader concept of performing the claimed method to achieve fertilization of eggs "in each of up to 75% of said multiple female bovine mammals" (i.e., in 10%, 20%, 30% etc).

As set forth in MPEP 2163(B), "New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic

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disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). In the present situation, the disclosure of a method of sorting sperm cells at a rate of 700-800 live sperm of each sex per second, concentrating the sorted sperm cells to a concentration of 3.36×10^6 sperm/ml, establishing an insemination sample of 184 microliters having 618,240 of the sorted sperm of the desired sex, and fertilizing a plurality of eggs in 9 out of 12 female bovine mammals does not provide support for the broader concepts recited in the claims of a method of sorting sperm cells at a rate of about 800 live sperm of each sex per second, concentrating the sorted sperm cells to a concentration of about 3.36×10^6 sperm/ml, establishing an insemination sample of about 184 microliters having about 618,240 of the sorted sperm of the desired sex, and fertilizing a plurality of eggs in up to 75% of female bovine mammals.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124, 133, 136 and 139-141 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 89-123, 153-160 and 163-175 of U.S. Patent Application No. 11/536,492 (published as PGPUB 2007/0026379). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '492 are both drawn to methods for producing multiple embryos from multiple female bovine mammals (and thereby producing multiple embryos from multiple female bovine mammals; see, e.g., claims 90, 154 and 164 of '492) wherein the methods comprise creating superovulation in female bovine mammals by injecting a dosage of a follicle stimulating hormone at half day increments at a dosage of 6, 6, 4, 4, 2, 2, 2, and 2 mg between days 9 and 12 inclusive of the estrus cycle, wherein prostaglandin F-2-alpha is also injected at 25 and 12.5 mg on the sixth and seventh dosages (see claims 106-108 of '492); collecting sperm cells from a male bovine; staining sperm cells with Hoechst 33342 (see claim 109 of '492; note that the '492 application defines the 38 um of stain, as recited in claim 109, as Hoechst 33342 stain - see para [0083] with respect to the PUGPUB 2007/0026379); sorting the sperm; concentrating the sperm; establishing an insemination sample of sperm cells of a desired sex; inserting at least one insemination sample into each bovine with half the dose into each uterine horn 20 to 24 hours post-onset of estrus (see, e.g., claims 93-95, 98 of '492); and fertilizing eggs in each of up to 75% of the bovine mammals (i.e., obtaining fertilization success rates of at least 35%, 41%, and at least 50% - see claim 175 of '492). With respect to the recitation in step d) of sorting sperm at a rate of about 800 live sperm of each sex per

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second, the claims of '492 recite sorting at rates of at least 1,200 sorts per second (claim 89 of '492). Since the present specification does not define the term "about" this term is considered to include higher sort rates of 1,200 sorts per second. Further, to determine the optimum conditions for performing a method step is well within the skill of the art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the optimum conditions for operating the flow cytometer, and thereby to have sorted the sperm at a rate of about 800 live sperm of each sex per second in order to have provided the most effective means for sorting the sperm.

With respect to the recitation in steps e) and f) of concentrating the sperm to a concentration of 3.36×10^6 sperm/ml and establishing an insemination sample of 184 ul containing about 618,240 sperm cells of the desired sex, the claims of '492 do not recite this particular limitation. However, the claims of '492 recite using a low dosage of sperm for insemination and particularly one half or 10 percent of the number of sperm relative to a typical insemination sample, and no more than 500,000 or no more than 1,000,000 sperm (claims 117-120). Accordingly, modification of the method of '492 to have particularly used an insemination sample having a concentration of about 3.36×10^6 sperm/ml and using about 184 ul containing about 618,240 sperm cells for insemination would have been obvious to one of ordinary skill in the art at the time the invention was

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made given the disclosure in the claims of '492 of performing insemination with a low dosage of sperm and no more than 1,000,000 sorted sperm.

With respect to present claim 139, the claims of '492 also include sorting sperm cells with a chemically coordinated sheath fluid so that the sheath fluid environment is coordinated with a pre-sort and post-sort cell fluid environment (see, e.g., claim 101 of '492).

With respect to present claim 140, the claims of '492 also include methods wherein the sheath fluid comprises citrate (see, e.g., claims 102 and 111 of '492).

With respect to present claim 141, the claims of '492 also include collecting sperm and cushioning the sperm from impact with a collection container that has a wide opening (e.g., claims 113-115 of '492).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634